



Food and Drug Administration
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Silver Spring, MD 20993-0002

January 8, 2015

SEBIA INC.
C/O MS. KAREN ANDERSON
DIRECTOR OF TECHNICAL AND QUALITY ASSURANCE
SUITE 400, 1705 CORPORATE DRIVE
NORCROSS GA 30093

Re: K143483

Trade/Device Name: MINICAP Immunotyping Using the MINICAP and the MINICAP
FLEX-PIERCING

Regulation Number: 21 CFR 866.5510

Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system

Regulatory Class: II

Product Code: CFF, DFH, DEH, CEF

Dated: December 8, 2014

Received: December 9, 2014

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Leonthena R. Carrington -A

Leonthena Carrington, MS, MBA, MT(ASCP)
Director (Acting)
Division of Immunology and Hematology Devices
Office of *In Vitro Diagnostics* and Radiological
Health (OIR)
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k143483

Device Name

MINICAP IMMUNOTYPING USING THE MINICAP AND THE MINICAP FLEX-PIERCING

Indications for Use (Describe)

The MINICAP IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human serum with the MINICAP and the MINICAP FLEX-PIERCING instruments, SEBIA, for capillary electrophoresis. It is used in conjunction with the MINICAP PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9).

The MINICAP and MINICAP FLEX-PIERCING instruments perform all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa and lambda (free and bound) light chains, respectively.

The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm.

The electrophoregrams are evaluated visually to detect the presence of specific reactions with suspected monoclonal proteins.

For In Vitro Diagnostic Use.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SPECIAL 510k SUMMARY

Purpose for Submission

Sebia hereby submits this Special 510k to provide notification of the modification to our MINICAP IMMUNOTYPING procedure. The MINICAP IMMUNOTYPING reagent kit was originally cleared for use with the MINICAP instrument, k082388 April 14, 2009.

This modification includes a new instrument family member, MINICAP FLEX-PIERCING.

Modifications to the test system include:

- New instrument family member MINICAP FLEX-PIERCING instrument using the MINICAP IMMUNOTYPING procedure.

A full description of the differences and similarities between performance of the MINICAP IMMUNOTYPING procedure using the MINICAP and MINICAP FLEX-PIERCING instruments is described below.

The MINICAP FLEX-PIERCING analyzer is a new member of the MINICAP family of analyzers and will use the same reagents as cleared with the MINICAP IMMUNOTYPING device.

The devices have the same intended use, detection and characterization of monoclonal proteins (immunotyping) in human serum using capillary electrophoresis.

Both devices are based on the same principles and technique following the process of:

- i. Each serum sample is mixed with the individual antisera that are specific against gamma (IgG), alpha (IgA), mu (IgM) heavy chains and kappa and lambda (free and bound) light chains.
- ii. The proteins are separated in silica capillaries and directly detected by their absorbance at 200 nm
- iii. The electrophorograms are evaluated to detect the presence of specific reactions with the suspected monoclonal proteins using PHORESIS software.

The MINICAP FLEX-PIERCING instrument was 510(k) cleared for an alternant assay MINICAP Hb A1c that has similar technical characteristic and the same software but a different sample matrix. The MINICAP Hb A1c was cleared under k133344, March 28, 2014

In accordance with the FDA policies, with this new application of the MINICAP IMMUNOTYPING assay using the MINICAP FLEX-PIERCING instrument, new labeling was added to the package insert. Sebia is following the FDA guidance to demonstrate the equivalence to the original reagent and instrument performance by using the Special 510(k) notification process.

The results of risk analysis employing acceptance criteria demonstrate the predetermined performance characteristics were met and the predetermined acceptance criteria were satisfied. The results indicate that the intended use, qualitative interpretation of the patterns were found substantially equivalent to the original device. The results demonstrate that the risk analysis demonstrates no adverse effects on the qualitative results obtained.

The Objectives of the modification was to:

- (i) Enable the MINICAP IMMUNOTYPING procedure to be run on another instrument family member the MINICAP FLEX-PIERCING instrument. This instrument was adapted for capped tube whole blood testing for MINICAP HbA1c technique and was cleared as k133344, March 28, 2014.

This objective was achieved by demonstrating the modifications that were adapted for the capped tube whole blood testing for MINICAP HbA1c testing at 415 nm did not affect the performance of the MINICAP IMMUNOTYPING procedure that uses serum and testing at 200 nm using *uncapped* tubes.

Acceptance criteria for the modified device were predetermined as follows:

1. The same intended use claim as the unmodified device
2. Substantial equivalency to the predicate device for the detection and characterization of the monoclonal proteins (immunotyping) in human serum.
3. Performance characteristics within predetermined criteria.

Completed detailed sets of data are on file at Sebia manufacturing

Device Name and Classification

Proprietary name: MINICAP IMMUNOTYPING using the MINICAP FLEX-PIERCING

Common name : Monoclonal Immunoglobulins by Capillary Electrophoresis

Classification: Class II

Product Regulation

21 CFR Part 866.5510 Immunoglobulins (A, G, M, D, E) Immunoglobulin test system

21 CFR Part 866.5550 Immunoglobulin (light chain specific) immunoglobulin test system

21 CFR Part 862.1630 Electrophoretic, Protein Fractionation

Product Code:

CFF- Immuno-electrophoretic, Immunoglobulins (G, A, M)

DFH- Kappa, Antigen, Antiserum Control

DEH- Lambda, Antigen, Antiserum Control

CEF- Electrophoretic, Protein Fractionation

Establishment Registration: Sebia is registration with the FDA is 8023024

Device Description

The MINICAP IMMUNOTYPING using the MINICAP FLEX-PIERCING instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoresis mobility in an alkaline buffer. The separation occurs according to the electrolyte pH and electro-osmotic flow. In capillary electrophoresis abnormal fractions in serum protein electrophoregrams, primarily those in the beta globulin and gamma globulin zones are always suspected of being monoclonal proteins (M-proteins, paraproteins, monoclonal immunoglobulins) and therefore an indication of a gammopathy. The MINICAP FLEX-PIERCING instrument has 2 capillaries functioning in parallel. A sample dilution is prepared and injected simultaneously by aspiration at the anodic end of the 2 capillaries.

The Immunotyping procedure follows the steps in which the sample is mixed with an ELP solution (reference pattern), specific antisera gamma (IgG) , alpha (IgA), mu (IgM) heavy chains and free/bound Kappa and Lambda light chains.

A high voltage protein separation is then performed and direct detection of the proteins at 200 nm at the cathodic end of the capillary. The capillaries are then washed and prepared for the next analysis. The superimposition of the antisera patterns with the ELP pattern allows for the visualization of the disappearance and /or the decrease of the monoclonal fraction on the antiserum pattern and to indicate a gammopathy.

Performance Standards

To date, no performance standards exist for this device

Intended Use

The MINICAP IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human serum with the MINICAP and the MINICAP FLEX-PIERCING instruments, SEBIA, for capillary electrophoresis. It is used in conjunction with the MINICAP PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9).

The MINICAP and MINICAP FLEX-PIERCING instruments perform all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa and lambda (free and bound) light chains, respectively.

The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm.

The electrophoregrams are evaluated visually to detect the presence of specific reactions with suspected monoclonal proteins.


For In Vitro Diagnostic Use.

Predicate device

We claim substantial equivalence to the MINICAP IMMUNOTYPING using the MINICAP instrument cleared as k082388.

Substantial equivalency Similarities

The table below demonstrates the similarities and differences between the MINICAP IMMUNOTYPING using the MINICAP instrument as compared to the MINICAP IMMUNOTYPING using the MINICAP FLEX-PIERCING instrument.

Feature	Predicate Device k082388 MINICAP IMMUNOTYPING using the MINICAP Instrument	Modified Device MINICAP IMMUNOTYPING using MINICAP FLEX-PIERCING Instrument
Intended Use	<p>The MINICAP IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human serum with the MINICAP System, SEBIA, for capillary electrophoresis. It is used in conjunction with the MINICAP PROTEIN(E) 6 kit, SEBIA, designed for protein separation into 6 major fractions in alkaline buffer (pH 9.9).</p> <p>The MINICAP performs all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each serum sample is mixed with individual antisera that are specific against gamma (IgG), alpha (IgA) and mu (IgM) heavy chains, and kappa and lambda (free and bound) light chains, respectively.</p> <p>The proteins, separated in silica capillaries are directly detected by the absorbance at 200 nm. The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspected monoclonal proteins.</p> <p>For In Vitro Diagnostic Use</p>	<p>The MINICAP IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human serum with the MINICAP and MINICAP FLEX- PIERCING instruments, SEBIA, for capillary electrophoresis. It is used in conjunction with the MINICAP PROTEIN(E) 6 kit, SEBIA, designed for protein separation into 6 major fractions in alkaline buffer (pH 9.9).</p> <p>The MINICAP and MINICAP FLEX- PIERCING instruments perform all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each serum sample is mixed with individual antisera that are specific against gamma (IgG), alpha (IgA) and mu (IgM) heavy chains, and kappa and lambda (free and bound) light chains, respectively.</p> <p>The proteins, separated in silica capillaries are directly detected by the absorbance at 200 nm. The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspected monoclonal proteins.</p> <p>For In Vitro Diagnostic Use</p>
Methodology	Capillary electrophoresis	Same
Technology	Capillary electrophoretic migration with Immunofixation by Subtraction(Immunotyping)	Same
Absorbance Wavelength	200 nm	Same
Sample Type	Serum	Same
Instrument Name	MINICAP PN 1230	MINICAP FLEX-PIERCING PN 1232
Instrument		
	Blue Cover	Green Cover
Instrument dimensions	22.6 X 16.2 X 16.9	17.3 X 16.3 X 22.8
Probe	Uncapped tubes only	Cap piercing

MINICAP IMMUNOTYPING using the MINICAP FLEX PIERCING instrument
SEBIA, January 2015

Probe Shape and Coating	Flat, Stainless Steel Teflon	Pointed, Stainless Steel slightly modified to enhance the hardness of the sample probe (addition of ceramic)
Detection	Deuterium lamp, network, U.V detector, optical fibers	Deuterium lamp, LED, network, U.V detector, optical fibers
Lamp	Deuterium lamp	Deuterium lamp with shape changed to allow space in the instrument for LED lamp (not used with this technique)
Tube requirement for Immunotyping	Uncapped	Uncapped
Capped and Uncapped Tubes (test dependent)	Not available for capped tubes	Yes
Loading of sample tubes	Sample tubes loaded onto rotating sampler wheel	Same
Sampling	Samples taken directly from the tubes (8 to 16 mm in diameter, 50 to 100 mm high) or from 1.5 ml microtubes positioned on the primary sample tubes. Sample volume: 10 to 20 µL	Same
Number of separation Units	2 parallel capillaries	Same
Sample identification	Yes, (Bar code reading of sample tubes)	Same
Introduction of samples into the automatic system	Continuous loading on the rotation sampler wheel	Same
Migration	Liquid-flow capillary electrophoresis in 2 silica capillary tubes. Migrations takes place in fully controlled temperature conditions using a Peltier device.	Same
Analysis throughput	2 samples/hour	Same
Software	PHORESIS	Same

MINICAP IMMUNOTYPING using the MINICAP FLEX PIERCING instrument
SEBIA, January 2015

CEBIA, January 2019

Reagent Labeling and composition	<table> <tr> <th>ITEMS</th> <th>PN 2300</th> </tr> <tr> <td>Sample diluent (ready to use)</td> <td>6 vials, 4.0 mL each</td> </tr> <tr> <td>Rack with ELP solution and antiserum tubes</td> <td></td> </tr> <tr> <td>ELP solution (ready to use)</td> <td>1 vial, 1.2 mL</td> </tr> <tr> <td>Mammalian immunoglobulins anti-human gamma heavy chains (ready to use)</td> <td>1 vial, 1.2 mL</td> </tr> <tr> <td>Mammalian immunoglobulins anti-human alpha heavy chains (ready to use)</td> <td>1 vial, 1.2 mL</td> </tr> <tr> <td>Mammalian immunoglobulins anti-human mu heavy chains (ready to use)</td> <td>1 vial, 1.2 mL</td> </tr> <tr> <td>Mammalian immunoglobulins anti-human kappa (free and bound) light chains (ready to use)</td> <td>1 vial, 1.2 mL</td> </tr> <tr> <td>Mammalian immunoglobulins anti-human lambda (free and bound) light chains (ready to use)</td> <td>1 vial, 1.2 mL</td> </tr> </table>		ITEMS	PN 2300	Sample diluent (ready to use)	6 vials, 4.0 mL each	Rack with ELP solution and antiserum tubes		ELP solution (ready to use)	1 vial, 1.2 mL	Mammalian immunoglobulins anti-human gamma heavy chains (ready to use)	1 vial, 1.2 mL	Mammalian immunoglobulins anti-human alpha heavy chains (ready to use)	1 vial, 1.2 mL	Mammalian immunoglobulins anti-human mu heavy chains (ready to use)	1 vial, 1.2 mL	Mammalian immunoglobulins anti-human kappa (free and bound) light chains (ready to use)	1 vial, 1.2 mL	Mammalian immunoglobulins anti-human lambda (free and bound) light chains (ready to use)	1 vial, 1.2 mL	Same											
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Antisera Specificity	Antibody specificity to heavy chains (IgG, IgA, IgM) and to light chains (Kappa , Lambda)	Same																														
Sensitivity	<table> <tr> <th rowspan="2">SAMPLE No.</th> <th colspan="2">MONOCLONAL COMPONENT</th> <th rowspan="2">CONCENTRATION (g/dL) (in the original serum)</th> <th rowspan="2">DETECTION LIMIT (mg/dL)</th> </tr> <tr> <th colspan="2">TYPE</th> </tr> <tr> <td rowspan="2">1</td> <td rowspan="2">Ig A, L</td> <td>Alpha</td> <td rowspan="2">2.7</td> <td>25</td> </tr> <tr> <td>Lambda</td> <td>25</td> </tr> <tr> <td rowspan="2">2</td> <td rowspan="2">Ig G, K</td> <td>Gamma</td> <td rowspan="2">2.9</td> <td>25</td> </tr> <tr> <td>Kappa</td> <td>25</td> </tr> <tr> <td rowspan="2">3</td> <td rowspan="2">Ig M, K</td> <td>Mu</td> <td rowspan="2">1.7</td> <td>25</td> </tr> <tr> <td>Kappa</td> <td>25</td> </tr> </table>			SAMPLE No.	MONOCLONAL COMPONENT		CONCENTRATION (g/dL) (in the original serum)	DETECTION LIMIT (mg/dL)	TYPE		1	Ig A, L	Alpha	2.7	25	Lambda	25	2	Ig G, K	Gamma	2.9	25	Kappa	25	3	Ig M, K	Mu	1.7	25	Kappa	25	Same
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			Kappa		25																											
	3	Ig M, K	Mu	1.7	25																											
Kappa			25																													
Buffer pH	pH 9.9			Same																												
Serum Sample volume required for dilution: dependants on the immunoglobulin concentration	<p>< 0.8 g/dL Ig: 40 µL of serum required to make 1:10 dilution</p> <p>0.8 -2.0 g/dL Ig: 20 µL of serum to make 1:20 dilution; and</p> <p>> 2.0 g/dL Ig: 20 µL of serum to make 1:40 dilution</p>			Same																												
Results	Qualitative Interpretation			Same																												

Proposed Labeling

The proposed labeling is attached in this submission. It includes:

- 1) MINICAP IMMUNOTYPING using the MINICAP FLEX-PIERCING instrument
- 2) MINICAP FLEX-PIERCING Instrument manual

Modifications to the MINICAP IMMUNOTYPING using the MINICAP FLEX-PIERCING instrument do not affect the intended use of the device as describe in the labeling, nor alter the fundamental scientific technology of the device. We trust that the information provided with this Special 510K will support the decision of substantial equivalence to the predicate for the MINICAP IMMUNOTYPING using the MINICAP FLEX-PIERCING instrument.

If additional questions or information is required please contact:
Karen Anderson, MT (ASCP)

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Scientific Affairs Officer
1-800-835-6497

Karen Anderson